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§ 94.5 Management of conflicting interests.

(a) The designated official(s) must: Review all financial disclosures; and determine whether a conflict of interest exists, and is so, what actions should be taken by the institution to manage, reduce, or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

- (1) Public disclosure of significant financial interests;
- (2) Monitoring of the research by independent reviewers;
- (3) Modification of the research plan;
- (4) Disqualification from participation in all or a portion of the research funded by the PHS;
- (5) Divestiture of significant financial interests, or;
- (6) Severance of relationships that create actual or potential conflicts.

(b) In addition to the types of conflicting financial interests described in this paragraph that must be managed, reduced, or eliminated, an Institution may require the management of other conflicting financial interests, as the Institution deems appropriate.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

§ 94.6 Remedies.

(a) If the failure of an Investigator to comply with the conflict of interest policy of the Institution has biased the design, conduct, or reporting of the PHS-funded research, the Institution must promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action or refer the matter to the institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the funded project.

(b) The HHS may at any time inquire into the Institutional procedures and

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actions regarding conflicting financial interests in PHS-funded research, including a review of all records pertinent to compliance with this part. HHS may require submission of the records or review them on site. To the extent permitted by law HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Awarding Component may decide that a particular conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with this part. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this part, the Institution must require disclosure of the conflicting interest in each public presentation of the results of the research.

[60 FR 35817, July 11, 1995; 60 FR 39077, July 31, 1995]

PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE, MEDICAL ASSISTANCE AND STATE CHILDREN'S HEALTH INSURANCE PROGRAMS)

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AUTHORITY: Sec. 452(a), 83 Stat. 2351, 42 U.S.C. 652(a); sec. 1102, 49 Stat. 647, 42 U.S.C. 1302; sec. 7(b), 68 Stat. 658, 29 U.S.C. 37(b); sec. 139, 84 Stat. 1323, 42 U.S.C. 2577b; sec. 144, 81 Stat. 529, 42 U.S.C. 2678; sec. 1132, 94 Stat. 530, 42 U.S.C. 1320b-2; sec. 306(b), 94 Stat. 530, 42 U.S.C. 1320b-2note, unless otherwise noted.

Subpart A—Time Limits for States To File Claims

SOURCE: 46 FR 3529, Jan. 15, 1981, unless otherwise noted.

§ 95.1 Scope.

(a) This subpart establishes a two year time limit (15 months in some cases) for a State to claim Federal financial participation in expenditures under State plans approved under the following titles of the Social Security Act:

Title I—Grants to States for Old-Age Assistance and Medical Assistance for the Aged.

Title IV-A—Grants to States for Aid and Services to Needy Families with Dependent Children (except for Section 402(a)(19)(G) of the Act).

Title IV-B—Child Welfare Services.

Title IV-D—Child Support and Establishment of Paternity.

Title IV-E—Foster Care and Adoption Assistance.

Title X—Grants to States for Aid to the Blind.

Title XIV—Grants to States for Aid to the Permanently and Totally Disabled.

Title XVI—Grants to States for Aid to the Aged, Blind, or Disabled (AABD), or for Such Aid and Medical Assistance for the Aged.

Title XIX—Grants to States for Medical Assistance Programs.

Title XX—Grants to States for Services.

Title XXI—Grants to States for State Children's Health Insurance Programs.

(b) This subpart also applies to claims for Federal financial participation by any State which are based on

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any provision of the Act that is enacted after issuance of these regulations and that provides, on an entitlement basis, for Federal financial participation in expenditures made under State plans or programs.

(c) This subpart explains under what conditions the Secretary may decide to extend the time limit for filing claims when a State believes it has good cause for not meeting the time limit.

[46 FR 3529, Jan. 15, 1981, as amended at 65 FR 33632, May 24, 2000]

§ 95.4 Definitions.

In this subpart—

Adjustment to prior year costs means an adjustment in the amount of a particular cost item that was previously claimed under an interim rate concept and for which it is later determined that the cost is greater or less than that originally claimed.

Audit exception means a proposed adjustment by the responsible Federal agency to any expenditure claimed by a State by virtue of an audit.

Claim means a request for Federal financial participation in the manner and format required by our program regulations, and instructions or directives issued thereunder.

Court-ordered retroactive payment means either a retroactive payment the State makes to an assistance recipient or an individual, under a Federal or State court order or a retroactive payment we make to a State under a Federal court order. Although we may accept these claims as timely, this provision does not mean that we necessarily agree to be bound by a State or Federal decision when we were not a party to the action.

Federal financial participation means the Federal government's share of an expenditure made by a State agency under any of the programs listed in § 95.1.

State means the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa and the Trust Territories of the Pacific.

State agency for the purposes of expenditures for financial assistance under title IV-A and for support enforcement services under title IV-D

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means any agency or organization of the State or local government which is authorized to incur matchable expenses; for purposes of expenditures under titles XIX and XXI, means any agency of the State, including the State Medicaid agency or State Child Health Agency, its fiscal agents, a State health agency, or any other State or local organization which incurs matchable expenses; for purposes of expenditures under all other titles, see the definitions in the appropriate program's regulations.

The Act means the Social Security Act, as amended.

We, our, and us refer to HHS's Centers for Medicare & Medicaid Services, Office of Child Support Enforcement, Office of Human Development Services, or the Social Security Administration, depending on the program involved.

[46 FR 3529, Jan. 15, 1981, as amended at 65 FR 33632, May 24, 2000]

§ 95.7 Time limit for claiming payment for expenditures made after September 30, 1979.

Under the programs listed in § 95.1, we will pay a State for a State agency expenditure made after September 30, 1979, only if the State files a claim with us for that expenditure within 2 years after the calendar quarter in which the State agency made the expenditure. Section 95.19 lists the exceptions to this rule.

§ 95.10 Time limit for claiming payment for expenditures made before October 1, 1979.

Under the programs listed in § 95.1, we will pay a State for a State agency expenditure made before October 1, 1979, only if the State filed or files a claim with us for that expenditure before January 1, 1981. Section 95.19 lists the exceptions to this rule.

§ 95.11 Payment of claims subject to appropriations restrictions.

Notwithstanding any other provision of this Subpart, we will pay States' otherwise allowable claims for Federal financial participation under the programs covered by this Subpart, subject to the availability of funds (as provided in Acts appropriating funds to the Department in effect at the time in which